

FORM PTO 1449 (modified)			ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/960,577			
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			APPLICANT Eugenio Cefali, et al.				
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)			FILING DATE 31 October 1997			GROUP 1615	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
DOCUMENTS SUBMITTED UNDER MPEP § 724							
<i>RECEIVED JAN 04 2005</i>							
<i>R</i>		Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) - Subject to Protective Order					<i>OFFICE OF PETITIONS</i>
<i>L</i>		Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] - Subject to Protective Order					
<i>L</i>		Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) - Subject to Protective Order					
<i>L</i>		Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004) - Subject to Protective Order					
<i>L</i>		Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] - Subject to Protective Order					
<i>L</i>		Expert Report of Don W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] - Subject to Protective Order					
<i>L</i>		Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] - Subject to Protective Order					
<i>L</i>		Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004) - Subject to Protective Order					
EXAMINER	<i>L Chanavajjhala</i>					DATE CONSIDERED	<i>12/29/05</i>

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/980,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		RECEIVED APPLICANT Eugenio Cefali, et al.	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		FILING DATE 31 October 1997 JAN 04 2005 OFFICE OF PETITIONS	GROUP 1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
DOCUMENTS SUBMITTED UNDER MPEP § 724			
<p>Rebuttal Expert Report of Thomas S. Foster, Pharm.D. (April 2, 2004) - Subject to Protective Order</p>			
<p>Rebuttal Expert Report of Thomas S. Foster, Pharm.D. Regarding The '967 Patent (October 4, 2004) - Subject to Protective Order</p>			
<p>Rebuttal Expert Report of James W. McGinity, Ph.D. (April 2, 2004) - Subject to Protective Order</p>			
<p>Supplemental Rebuttal Expert Report of James W. McGinity, Ph.D. (August 18, 2004) - Subject to Protective Order</p>			
<p>Rebuttal Expert Report of James W. McGinity, Ph.D. Regarding The '967 Patent (September 30, 2004) - Subject to Protective Order</p>			
<p>Expert Report of Mark E. McGovern, M.D. (February 6, 2004) - Subject to Protective Order</p>			
<p>Expert Report of Mark E. McGovern, M.D. (August 20, 2004) - Subject to Protective Order</p>			
<p>Expert Report of Frank M. Sacks, M.D. (April 2, 2004) - Subject to Protective Order</p>			
<p>Expert Report of Frank M. Sacks, M.D. (August 20, 2004) - Subject to Protective Order</p>			
<p>Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004) - Subject to Protective Order</p>			
<p>Rebuttal Expert Report of Mary Ann Tucker, Esq. Regarding The '967 Patent (October 1, 2004) - Subject to Protective Order</p>			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
 Include copy of this form with next communication to applicant.

L. Channavajjale 12/29/05

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/880,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		APPLICANT Eugenio Cefalo, et al.	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		FILING DATE 31 October 1997	GROUP 1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
DOCUMENTS SUBMITTED UNDER MPEP § 724			
		Sample Kos Clinical Trial Medical Consent Form - Subject to Protective Order	
		Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order	
EXAMINER	L. Channavajala	DATE CONSIDERED	12/29/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/980,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		RECEIVED	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		FILING DATE 31 October 1997 JAN 04 2005	GROUP OFFICE OF PETITIONS 1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
<p><i>✓</i></p> <p>Carl J. Lavie, et al., Marked Benefit with Sustained-Release Niacin Therapy in Patients with "isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease, Am. J. Cardiol. 1992;69:1083-1085</p>			
<p>Excerpts from the 1993, 2000 and 2002 editions of the Physician's Desk Reference 1993 edition (pp. 434, 611, 856, 1189, 1919, 1920, 2491 and 2492) 2000 edition (pp. 1519-1523) 2002 edition (pp. 1846-1850)</p>			
<p>Niacin: Double-edged Sword for Lowering Cholesterol, Tufts University Diet & Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6</p>			
<p>Larsen, ML and Illingworth, DR, Drug Treatment of Dyslipoproteinemia, Med Clin N Am., 78:225-245 (1994)</p>			
<p>Lavie, Letter to Editor, JAMA 1994; 272:513-515</p>			
<p>Keenan, Letter to Editor, JAMA 1994; 272:513-515</p>			
<p>Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515</p>			
<p>Thomas N. Tozer, Clinical Pharmacokinetics Concepts and Applications (3d ed. 1995) at Chapter 9, p. 120</p>			
<p>Excerpts from the 1995 United States Pharmacopeia (pp. iii-vi, 1080-1082, 1793-1799, 1940-1944)</p>			
<p>Morgan & Capuzzi Abstract, Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin, Clinical Pharmacology & Therapeutics (February 1996)</p>			
<p>Morgan & Capuzzi Article, Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial, J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996)</p>			
EXAMINER	<i>L. Channavajjala</i>		DATE CONSIDERED <i>12/29/05</i>

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/860,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		APPLICANT Eugenio Cefalo, et al.	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		FILING DATE 31 October 1997	RECEIVED JAN 04 2005 GROUP 1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Periodicals, Etc.)			
Capuzzi DM, et al., Efficacy and Safety of An Extended-Release Niacin (Niaspan): A Long-Term Study, Am J Cardiol. 1998;82:74U-81U			
Guyton JR, Advances in Dyslipidemia: Discussion Session II, Am J Cardiol, 1998: 82(12A): 85U-86U			
Knopp RH, et al., Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia, Metabolism 47:1097-1104 (1998)			
American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 21:179-182, 1998			
Elam MB, et al., Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease, JAMA: 2000; 284:1263-1270			
Kesala R, et al., Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP), Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000)			
2001 NCEP Report at VI-11, Table VI.2-3			
Wang, W. et al., Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production, Am J Physiol Endocrinol Metab., 280:E540-E547 (2001)			
Smith SC, et al., AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update. AHA/ACC Scientific Statement, 1577-79			
Tavintharan S and Kashyap M, The Benefits of Niacin in Atherosclerosis, Curr Athero. Reports 2001; 3:74-82			
EXAMINER	<i>L Channavajpe</i>	DATE CONSIDERED	<i>12/29/05</i>

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/680,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		RECEIVED	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		FILING DATE 31 October 1997	JAN 04 2005 GROUP 1615
OFFICE OF PETITIONS			
<p>OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)</p> <p><i>Meadows M., Serious Liver Injury: Leading Reason for Drug Removals, Restrictions, FDA Consumer Magazone, May-June 2001; http://www.fda.gov/fdac/features/2001/301_liver.html</i></p> <p><i>Grundy SM, et al., Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes. Arch Intern Med. 2002; 162: 1568-1576</i></p> <p><i>American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 25:S74-S77, 2002</i></p> <p><i>Pan J, et al., Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes, Diabetes, Obesity and Metabolism 4:255-261 (2002)</i></p> <p><i>Pan J, et al., Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes, Metabolism 51:1120-1127 (2002)</i></p> <p><i>Meyers CD, et al., Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia, Ann Intern Med. 2003; 139:996-1002</i></p> <p><i>CDER Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (March 2003)</i></p> <p><i>American Diabetes Association: Dyslipidemia Management in Adults with Diabetes, Diabetes Care 27:S68-S71, 2004</i></p>			
EXAMINER <i>L. Channarayajala</i>		DATE CONSIDERED	<i>12/29/05</i>

Form #62

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.